



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

FEB 23 2018

Re: PMN P-17-0281

Dear [REDACTED]

This letter provides you notice of the United States Environmental Protection Agency's (EPA's) intent to issue a significant new use rule (SNUR) under section 5(a)(2) of the Toxic Substances Control Act (TSCA), 15 U.S.C. § 2604(a)(2), for the chemical substance (Polysiloxane-polyester polyol carboxylate) described in the premanufacture notice (PMN) referenced above.

EPA's initial review indicates that the chemical substance is not likely to present an unreasonable risk of injury to health or the environment under the conditions of use described in the PMN (including any amendments). However, EPA has preliminarily determined that reasonably foreseen changes from the conditions of use described in the PMN could result in "increased volume of manufacturing and processing of the chemical substance" AND/OR "increased exposures to the chemical substances" AND/OR "changes in the reasonably anticipated manner and methods of manufacturing, processing, distribution in commerce, and disposal of the chemical substances".

In reviewing this PMN, EPA identified human health concerns from exposure to the chemical substance via dermal route which would be present if the chemical substance were used in a manner other than as identified in the PMN. The concern is based on test data or ecological structure-activity relationship (ECOSAR) analysis of test data for the chemical or equivalent information on an analog.

EPA expects to determine, pursuant to TSCA section 5(a)(3)(C), 15 U.S.C. § 2604(a)(3)(C), that the PMN substance is not likely to present an unreasonable risk of injury to health or the environment, based on the data before the Agency and the risk assessment conducted for the conditions of use identified in the PMN, and because any reasonably foreseen activities involving the chemical substance would require further notification and evaluation by EPA under section 5(a) of TSCA.

The SNUR would establish the following as significant new uses in 40 C.F.R. 721 Subpart E for the new chemical substance:

- (i) *Protection in the workplace.* Requirements as specified in § 721.63 (a)(1), (a)(2)(i), (a)(2)(iii), (a)(3), (b)(concentration set at 1.0%), and (c).
- (ii) *Industrial, commercial, and consumer activities.* Requirements as specified in §

721.80 (j).

The SNUR would require submission of a significant new use notice (SNUN) to EPA at least 90 days before:

- i) any use other than as [REDACTED] and [REDACTED]
- ii) any use without dermal protection for workers.

The recordkeeping requirements described at 40 C.F.R. § 721.125(a), (b), (c), (d), (e), (h) and (i) would also be applicable to the chemical substance. The SNUR would apply to all persons, including to your company, your customers for the chemical substance, and any other manufacturer or processor of the chemical substance.

Section 5(a)(1)(B) of TSCA, 15 U.S.C. § 2604(a)(1)(B), provides that no person (including you, the PMN submitter) may manufacture (including import) or process a chemical substance for a use designated by EPA as a "significant new use" unless that person submits a SNUN to EPA, and EPA reviews that notice and makes a determination pursuant to section 5(a)(3) of TSCA, 15 U.S.C. § 2605(a)(3). This review requires EPA to assess potential risk under the conditions of use and impose any appropriate regulatory control actions.

For many SNURs, the preamble in the Federal Register notice for the SNUR suggests testing that would be useful to EPA's evaluation in the event that someone submits a SNUN for the significant new use. Companies who submit SNUNs are encouraged, but not required, to conduct the suggested testing on the substance. Any testing identified by EPA for your chemical substance that would be useful will be specified in the preamble.

If you choose not to suspend the review period, EPA may not be able to use the SNUR as part of the basis for its section 5(a)(3) determination, and the Agency might be required to issue an order under section 5(e) or section 5(f) of TSCA. In order for there to be sufficient time to issue the SNUR, the Agency requests that you suspend the PMN review period until EPA issues the SNUR and makes the final section 5(a)(3) determination.

If you have any questions or comments, please contact Kenneth Moss, the SNUR Team Leader, at (202) 564-9232.

Sincerely,



Greg Schweer, Chief
New Chemicals Management Branch
Chemical Control Division (7405 M)